Paieon Inc.

APR - 2 2004

K993139

510(k) SUMMARY—CardiOp-B System

Submitter Name:	Paieon Inc.
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Date Prepared:	07/01/2003
Device Trade Name:	The CardiOp-B System
Device Common Name:	3D Vessel Analysis System
Classification Name:	Accessory to x-ray angiographic system
Predicate Devices:	QCA-CMS by MEDIS Medical Imaging Systems Inc. (K993763)
Device Description:	The CardiOp-B System is an image acquisition and processing software system designed as an add-on to conventional X-ray angiography systems. The CardiOp-B system presents a three-dimensional reconstruction of the stenosed vessel as well as quantitative cross-section information. The system includes a software package that runs on off-the-shelf hardware. CardiOp-B's features and benefits include 3D reconstruction, real-time and quantitative measurements.
Intended Use:	The CardiOp-B System is an add-on system to single plane angiography that assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on 2D angiography images. CardiOp-B provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image. CardiOp-B is intended for use in real-time in the catheterization lab and off-line for post-procedural analysis.

K030139

Device Technological Characteristics and Comparison to Predicate Device(s):	The CardiOp-B system is comprised of software that runs on the Windows XP operating system. The QCA-CMS system runs on Windows NT. The CardiOp-B system analyzes 2-3 angiography images to create a 3D image as well as quantitative data of vessel segments, while the QCA-CMS system analyzes a single angiography images. Quantitative parameters that are presented by the CardiOp-B system are based on cross-sectional area measurements while the quantitative parameters that are presented by QCA-CMS are based primarily on a diameter analysis.
Performance Data:	Validation on phantoms produced overall accuracy and precision results within the predetermined specifications and comparable to those achieved with currently marketed QCA systems. The CardiOp-B system has been tested on clinical images and results compared to those of the predicate QCA device. There is a correlation between the Minimal Lumen diameter as well as Length results between the systems.
Conclusion:	The CardiOp-B system provides accurate and precise results for area, diameter, and length on phantoms. The skeleton of the 3D reconstruction that is created by the system is comparable to the skeletons of 2D images of the vessel in terms of its spatial distribution. Furthermore, the CardiOp-B system is able to analyze clinical images and provide diameter and length results that correlate to those of an FDA approved QCA system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Mr. Omer Barlev
CEO
Paieon Medical, Inc.
747 Third Ave., 4th Floor
NEW YORK NY 10017-2803

Re: K030139
Trade/Device Name: The CardiOp-B System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: 90 IZI
Dated: March 22, 2004
Received: March 22, 2004

Dear Mr. Barlev:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): TBD K030139

Device Name: The CardiOp-B System

Indications for Use:

The CardiOp-B System is a software system that assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. CardiOp-B provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image. CardiOp-B is intended for use in real-time in the catheterization lab and off-line for post-procedural analysis. It is intended for use by clinicians, technicians and research personnel

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030139